WHY INTELLECTUAL PROPERTY REFORM IN SOUTH AFRICA WILL HELP NOT HURT ECONOMIC DEVELOPMENT AND INNOVATION IN THE COUNTRY

A policy paper of Fix the Patent Laws Campaign

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Fix the Patent Laws is a joint coalition of the Treatment Action Campaign (TAC), Doctors Without Borders (MSF), SECTION27, Cape Mental Health (CMH), Diabetes SA, Epilepsy SA, Health GAP, Marie Stopes South Africa, the Stop Stock Outs Project (SSP), the Schizophrenia and Bipolar Disorders Alliance (SABDA), the South African Depression and Anxiety Group (SADAG), the South African Federation of Mental Health (SAFMH), the South African Non-Communicable Diseases Alliance (SANCD Alliance) and the Cancer Alliance including Advocates for Breast Cancer; amaBele Project Flamingo, Ari's Cancer Foundation, Breast Course 4 Nurses (BCN), Breast Health Foundation (BHF), Cancer Association of South Africa (CANSA), Cancer Heroes, CanSir, CanSurvive Cancer Support (CanSurvive), Care for Cancer Foundation, Childhood Cancer Foundation of South Africa (CHOC), Gladiators of Hope, Hospice Palliative Care Association (HPCA), Lymphoedema Association of South Africa (LAOSA), Look Good Feel Better (LGFB), Love Your Nuts (LYN), Men's Foundation, National Council Against Smoking, National Oncology Nursing Society of SA (NONSA), Pancreatic Cancer Network of SA (PanCan), People Living With Cancer (PLWC), the Pink Parasol Project, Pink Trees for Pauline (Pink Trees), Pocket Cancer Support, Rainbows and Smiles, Reach for Recovery (RFR), South African Oncology Social Workers' Forum (SAOSWF), The Sunflower Fund (TSF), VREDE Foundation for Young People with Cancer (Vrede Foundation) and Wings of Hope (WoH).

Intellectual property is considered as one of the tools that countries may use to stimulate innovation and creativity. In terms of inventions, the patents system provides for an exclusive right (patent) to be granted, by the state, to an inventor for their invention. During the period patent protection, no one else can make, use, import, market or sell the patented product other than the right-holder. The benefits of a patent system and its ability to stimulate socially beneficial innovation, especially in relation to health care, has been a contentious issue between industry, academics and health activists, and in many cases, has been the instigator for patent regime reforms. It has also been the subject of extensive research.

In South Africa, the Fix the Patent Laws Coalition[1] (FTPL) has conducted research on how amending the South African Patents Act would contribute to making medicines more accessible to those who need them. FTPL also lobbied the Department of Trade and Industry to develop an intellectual property policy that addresses the shortcomings of the current legal framework in a way that fulfils the constitutional promise to access health care services.

In 2018, after close to a decade of lobbying, Cabinet adopted a new intellectual property policy which will be implemented in phases. Phase I proposes some critical health-related policy and legislative changes. These proposals have been vigorously opposed by many, including the free market foundation, on the basis that reforms to the current framework would hamper innovation and affect foreign direct investment. This paper addresses some of the commonly held beliefs about patents which have been used to defend the status quo and oppose the implementation of the new policy.

[1] The coalition was established by Doctors Without Borders, SECTION27 and the Treatment Action Campaign.

Introduction

Sensible reforms to South Africa's patent laws will not harm the economy or inhibit domestic innovation. To the contrary, in this paper we provide evidence that sensible reforms can both stimulate the economy and bolster innovation – all while improving the access that people living in South Africa have to life-saving and life-changing medicines. The suggestion that legislators have to choose between patients and the economy is incorrect. The choice is between the interests of foreign pharmaceutical firms and their governments, on the one hand, and on the other, the expansion of the South African economy and the fulfilment of the government's Constitutional obligation to take reasonable legislative and other measures to progressively realise the right to access health care services.

Context is important. At present, South Africa's intellectual property framework is heavily slanted in favour of large foreign pharmaceutical companies and against domestic industry and patients. South Africa's rate of approving patent applications is currently much higher than most countries, rich or poor. Many patents granted in South Africa are rejected in other countries for failing to meet patentability criteria - the criteria of novelty, inventiveness and usefulness, which are required for a patent to be granted. The granting of patents on applications with dubious claims of novelty, inventiveness and usefulness places high social, financial and health costs on the country. In short, South Africa is allowing many patent monopolies to exist where we are not receiving any real innovation in return.

To address the shortcomings of South Africa's patent laws which allow for exploitation and rent seeking by large foreign corporations at the expense of public interest and access to medicine, South Africa is undertaking a process of patent law reform.

On 23 May 2018, the South African cabinet adopted the Intellectual Property Policy of the Republic of South Africa: Phase 1. The new IP policy commits to key patent law reforms "that will promote a holistic, balanced and coordinated approach to IP that is mindful of the many obligations mandated under the South African Constitution."

The changes proposed by the policy, and its adoption by cabinet is not unusual. The history of IP is full of examples where countries adapted the rules to suit their changing needs.

SOUTH AFRICA IS AN OUTLIER WITH REGARDS TO ITS HIGH RATE OF GRANTING PATENTS

Sampat and Sheldon demonstrated that South Africa is an anomaly regarding its high patent grant rate. In a review of matching patent applications filed in multiple jurisdictions between 2000 and 2002, South Africa granted 93% of patents applied for, versus 61% in the US, 51% in Europe and 29% in Japan. Sampat and Sheldon concluded that *"since South Africa does not examine applications, the only applications not granted there are those withdrawn during the examination process due to failure to pay issue fees, and (a very small number) applications still pending"* [2]

Correa demonstrated that South Africa's high pharmaceutical patent grant rate stands out in comparison to other developing countries with similar economic and social needs. In 2008 alone, South Africa granted 2,442 pharmaceutical patents, while Brazil granted only 278 pharmaceutical patents between 2003 and 2008. Correa explained that *"in South Africa patents are simply registered without verifying a priori if they meet or not the patentability requirements. This explains why South Africa appears with such a comparatively large number of patents issued in one single year"*.[3]

The policy clarifies that South Africa will develop and adopt patentability criteria that promote genuine innovation and implement examination procedures to ensure patents are granted only to applications meeting patentability criteria. Currently, South Africa grants patents without review of the merits of the application to determine whether it meets patentability criteria. As a result, South Africa routinely grants patents that are rejected or granted on a smaller scope of protection following rejection of the larger claim in other jurisdictions that substantively examine patent applications.[4]

[2] Sampat B, Sheldon K., (2016) 'The Effects of Restrictions on Secondary Pharmaceutical Patents: Brazil and India in Comparative Perspective.' https://www.semanticscholar.org/paper The-Effects-of-Restrictions-on-Secondary-Patents-%3A-Sampat-Shadlen/45271e5d7c002400d4e3a8a6baff1fd75a9db583.

[3] Correa C, (2011) 'Pharmaceutical Innovation, Incremental Patenting and Compulsory Licensing.' http://apps.who.int/medicinedocs/documents/s21395en/s21395en.pdf.

[4] Tomlinson C, Moyo H, Rizvi Z, Waterhouse C, Meyer S, Low M., (2018) 'Exploring patent barriers to cancer treatment access in South Africa: 24 medicine case studies' - https://www.canceralliance.co.za/wp-content/uploads/2017/10/Exploring-Patent-Barriers-to-Cancer-Treatment-Access-in-SA-24-Medicine-Case-Studies-October-2017.pdf.
See also: Tomlinson C, Hu Y Q , Hill J, and Waterhouse C (2016) 'Patent Barriers to Medicine Access in South Africa: A Case for Patent Law Reform' - https://www.fixthepatentlaws.org/wp-content/uploads/2016/09/MSF-FTPL-report-FINAL-VERSION.pdf.

In addition to strengthening patentability criteria and adopting substantive examination procedures, South Africa plans to establish more useable procedures for granting compulsory licenses. Compulsory licensing allows governments to grant licenses to protect public interest with royalty payments to the patent holder and has been used to protect public interest in multiple jurisdictions, including the United States.[5] However, compulsory licensing has never been used in South Africa due to a combination of overly complex, unworkable procedures for granting these types of licenses[6] and political pressure against their use.[7]

The planned reforms to South Africa's patent laws have been welcomed by Fix the Patent Laws (a coalition of 40 patient groups) as a critical step towards improving equitable medicine access in the country. Fix the Patent Laws has called for the rapid introduction of Bills to reform South Africa's laws in line with its policy commitments.

However, those who support strict intellectual property (IP) protections have criticised the policy and raised alarming claims that the proposed reforms will harm economic development and innovative progress within the country. They advocate for countries to expand and maximise IP protections beyond what is required by the World Trade Organisation's Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS). Importantly, these proponents often represent, or receive funding from, wealthy countries and industries seeking to maximise their trade surpluses and/or profits by lobbying for expanded IP protections in foreign countries where they sell goods and services, including South Africa. Groups that have applied concerted pressure on South Africa to provide IP protections beyond what is required by TRIPS include (among others) the American Chamber of Commerce,[8] the European Union[9] and pharmaceutical trade and lobby groups, including PhRMA[10] and IPASA.[11]

This paper responds to a number of claims made by about the benefits of adopting stringent IP systems, by highlighting evidence debunking these claims and demonstrating how the proposed reforms to South Africa's patent laws will boost, not harm, economic development and innovation in the country.

WHAT IS TRIPS AND WHY WAS IT ADOPTED?

The Agreement on Trade-Related Aspects of Intellectual Property Rights – also known as TRIPS – is an agreement that sets out the standards of intellectual property protection that World Trade Organisation (WTO) members are required to provide. South Africa has been a member of the WTO since its establishment in 1995. TRIPS adoption by WTO members in 1995 was championed by wealthy countries seeking to link IP protections to trade rules in order to secure greater global protections for their industries. TRIPS proponents argued that countries would generate economic growth and innovation by expanding intellectual property (IP) protections. However, evidence demonstrates significant shortcomings of IP protections in delivering economic growth and innovative progress - particularly in developing countries - and shows that overly stringent (maximal) IP protections can hurt rather than advance economic development and innovation.

[5] Stirner B (2013) 'Learning for Practice: Compulsory Licensing Cases and Access to Medicines'. DOI: 10.4155/ppa.12.91.https://www.ncbi.nlm.nih.gov/pubmed/24237026.
See also Third World Network. (2014). TWN Info Service on Health Issues. https://www.twn.my/title2/health.info/2014/hi140302.htm.

[6] United Nations Development Programme (2013) 'Using Law to Accelerate Treatment Access in South Africa' https://www.undp.org/content/undp/en/home/librarypage/hiv-aids/using-law-to-accelerate-treatment-access-in-south-africa.html.

[7] Beall R and Kuhn R., (2012) 'Trends in Compulsory Licensing of Pharmaceuticals Since the Doha Declaration: A Database Analysis.' https://journals.plos.org/plosmedicine/article?id=10.1371/journal.pmed.1001154.

[8] Fix the Patent Laws (2015) 'Pharma attempts to undermine South African patent law reform and access to medicines.' https://www.fixthepatentlaws.org/dont-trade-away-our-health-pharma-attempts-to-undermine-south-african-patent-law-reform-access-to-affordable-medicines/.

[9] Fix the Patent Laws (2015) 'Doctors Without Borders responds to the EU's submission on SA's Draft National IP Policy.' https://www.fixthepatentlaws.org/doctors-without-borders-responds-to-the-eus-submission-on-sas-draft-national-ip-policy/.

[10] Baker B, (2014) 'US PhRMA bares its fangs – South African patent law reform and access to medicine at risk yet again.' https://www.fixthepatentlaws.org/us-phrma-bares-its-fangs-south-africa-patent-law-reform-and-access-to-medicine-at-risk-yet-again/.

[11] De Wet P, (2014) Mail & Guardian 'Motsoaledi: Big pharma's 'satanic' plot is genocide.' https://mg.co.za/article/2014-01-16-motsoaledi-big-pharmas-satanic-plot-is-genocide/.

MYTHS RELATED TO IP

It has been argued that IP incentives are necessary to stimulate and reward innovation and that 'strong' IP systems will advance economic development, including through fostering local innovation, local industry and attracting foreign direct investment. We respond to these claims below, highlighting how overly stringent IP protections can be harmful for economic development and growth – while placing large social, financial and health cost on countries.

MYTHS DEBUNKED MYTHS

A more flexible IP system will not hamper economic development

Myth: Strong/Strict IP protection will promote economic development

Debunked: Highly industrialised and developed economies such as the US, Europe and the Asian Tigers deliberately instituted weak IP protections to facilitate industrial and economic development.

While claims that maximum IP protections will advance economic development, IP historians and economists have demonstrated that this claim is not supported by evidence. Multiple academics have shown that many of today's developed economies, including the U.S. and Europe, provided weak intellectual property protections while transitioning into highly industrialized, developed economies.[12] Baker et al., explained that *"by the standards of today's global rules, every advanced industrialised country would have been classified as an intellectual property violator at the early stages of development when they freely used ideas and technologies generated elsewhere"*.[13]

Academics have further demonstrated how relatively low levels of IP protection, prior to TRIPS adoption, allowed for rapid technological and economic development in several Asian countries, including Japan, South Korea and Taiwan. According to academics, technological capacity acquired and absorbed during periods of weak IP protection was critical to transitioning key industries in Asia from imitative to innovative production.[14] Kumar explains that "*Japan, Korea and Taiwan... absorbed substantial amounts of technological learning under weak IPR protection regimes during the early phases [of development]. These patent regimes facilitated the absorption of innovation and knowledge generated abroad by their indigenous firms*".[15] Chen adds that *"today, Samsung in South Korea is one of the world's top enterprises and Taiwan is also home to many world-class producers"*.[16]

Given the evidence that weak IP protection and enforcement facilitated industrial and economic development in developed economies, wealthy countries have been accused of "kicking away the ladder" that would allow developing countries to catch up by pressuring these countries to ramp up IP protections that

[12] Chang HJ, (2002) 'Kicking away the ladder: Development Strategy in Historical Perspective'. http://www.personal.ceu.hu/corliss/CDST_Course_Site/Readings_old_2012_files/Ha-Joon%20Chang%20-%20Kicking%20Away%20the%20Ladder The%20%E2%80%9CReal%E2%80%9D%20History%20of%20Free%20Trade.pdf.
See also Baker D, Jayadev A, and Stiglitz J., (2018) 'Innovation, Intellectual Property, and Development: A Better Set of Approaches for the 21st Century' http://ip-unit.org/wp-content/uploads/2017/07/IP-for-21st-Century-EN.pdf.
See also Odagiri H, Goto A, Sunami A, and Nelson R. (2011) 'Intellectual Property Rights, Development and Catch-up' The Economic History Review. 64. 1065-1066. 10.2307/41262517.
See also Maskus KE (2004) 'Encouraging International Technology Transfer.' https://www.iprsonline.org/resources/docs/Maskus%20-%20Encouraging%20International%20ToT-%20Blue%207.pdf.

[13] Baker D, Jayadev A, and Stiglitz J., (2018) 'Innovation, Intellectual Property, and Development: A Better Set of Approaches for the 21st Century' http://ip-unit.org/wp-content/uploads/2017/07/IP-for-21st-Century-EN.pdf.

[14] Odagiri H, Goto A, Sunami A, Nelson R. (2011) 'Intellectual Property Rights, Development and Catch-up.' The Economic History Review. 64. 1065-1066. 10.2307/41262517.
See also Kumar N, (2003) 'Intellectual Property Rights, Technology and Economic Development: Experiences of Asian Countries.' Economic and Political Weekly 38 (3) 209-215+217-226.

[15] Kumar N, (2003) 'Intellectual Property Rights, Technology and Economic Development: Experiences of Asian Countries.' Economic and Political Weekly 38 (3) 209-215+217-226.

[16] Chen SCY (2014) 'Pirate Production, Intellectual Property and Informal Sector in Developing Economies' https://www.taylorfrancis.com/books/e/9781315817491/chapters/10.4324/9781315817491-14.

constrain the use of knowledge and technology.[17] Okediji notes that *"heftier rules in the TRIPS Agreement reconfigured the terms of access to knowledge goods in ways that increased the technological gap between the global south and the global north and resulted in wealth transfers to net exporters of technology"*, adding that *"the technologies of the Fourth Industrial Revolution may produce the same outcomes, despite how revolutionary and beneficial those technologies are expected to be to the creative process"*.[18]

In South Africa there is substantial scope to foster economic growth through industrialisation and digitisation. A more flexible IP system that allows for borrowing, absorption and copying of technologies developed elsewhere can enable growth in South Africa, and allow the country to participate more fully in and benefit from the Fourth Industrial Revolution – rather than being locked into the role of customer/purchaser of technologies developed and owned in other countries.

Strong IP protections protect local industries

Myth: Strong IP protections encourage growth of local industry.

Debunked: Weak IP protections and adoption of TRIPS flexibilities can foster economic growth through industrialisation and digitisation. See for example growth of the pharmaceutical industry in India.

Another claim is that strict IP protection is necessary to protect and grow local industry, there is limited evidence to support this claim in developing country contexts.[19] In fact, evidence demonstrates that weak IP protection and enforcement can play a role in growing local industry in countries with the ability to creatively absorb, imitate and produce existing technologies.

For example, weak IP enforcement enabled the development of competitive local cellular and solar technologies and industries in China.[20] And, in India, the absence of IP protections on pharmaceuticals was key to the explosive growth of the country's generic pharmaceutical industry. As noted by Kilic:*"it is widely accepted that this lack of patent protection, particularly for pharmaceutical products, was a key to the growth of the generic industry in India"*.[21] Patent laws adopted in India in 1970 prohibited patenting of pharmaceuticals and (unlike South Africa) India fully utilized extension periods for TRIPS implementation, not providing patents on pharmaceuticals until 2005. India's generic pharmaceutical industry flourished during the years that it did not provide pharmaceutical patents. India was a net importer of medicines until 1988, but by the mid-90s India reversed this deficit, generating a large trade surplus.[22] Today, India retains its dominance as a global generic supplier and is commonly referred to as the pharmacy of the developing world.[23]

Strict IP protections have arguably hampered growth of South Africa's local pharmaceutical industry, which predominately develops finished generic products, by preventing local companies from entering the market during extended patent monopoly periods. Importantly, efforts by patient groups to overcome patent barriers to medicine access have also had the added benefit of supporting the growth of local industry. For example, competition commission complaints by the Treatment Action Campaign (TAC) related to patents on the antiretroviral medicines nevirapine and efavirenz led to the licensing and introduction of generic products in 2004 and 2008 respectively. (The primary patents on nevirapine and efavirenz expired in South Africa in 2010 and 2013, respectively). Generic companies licensed as a result of TAC's complaints included the local pharmaceutical producer Aspen, which won 100% and 30% of South Africa's 2008 antiretroviral tender (the largest globally) for nevirapine and efavirenz, respectively.[24] Without efforts by TAC to overcome patent barriers to HIV medicine access, Aspen would have been unable to compete in the 2008 tender for either nevirapine or efavirenz.

Evidence also clearly demonstrates that the adoption and use of TRIPS flexibilities can enable growth of local industry, particularly in the pharmaceutical sector. The potential of TRIPS flexibilities to

[17] Chang HJ, (2002) 'Kicking away the ladder: Development Strategy in Historical Perspective.' http://www.personal.ceu.hu/corliss/CDST_Course_Site/Readings_old_2012_files/Ha-Joon%20Chang%20-%20Kicking%20Away%20the%20LadderThe%20%E2%80%9CReal%E2%80%9D%20History%20of%20Free%20Trade.pdf.

[18] Okediji R, (2018) 'Creative markets and copyright in the fourth industrial era.' https://www.ictsd.org/sites/default/files/research/creative_markets_and_copyright_in_the_fourth_industrial_era-okediji-ictsd_final_0.pdf.

[19] Baker D, Jayadev A, and Stiglitz J., (2018) 'Innovation, Intellectual Property, and Development: A Better Set of Approaches for the 21st Century.' http://ip-unit.org/wp-content/uploads/2017/07/IP-for-21st-Century-EN.pdf.

[20] Baker D, Jayadev A, and Stiglitz J., (2018) 'Innovation, Intellectual Property, and Development: A Better Set of Approaches for the 21st Century.' http://ip-unit.org/wp-content/uploads/2017/07/IP-for-21st-Century-EN.pdf.

[21] Kilic B, (2011) 'Boosting Pharmaceutical Innovation in the Post-TRIPS Era.' https://www.tandfonline.com/doi/abs/10.1080/2157930X.2011.556484?journalCode=riad20.

[22] Shah D (year) 'Focus Asia. Generic to Innovative: Transition of Indian Pharmaceutical Companies.' https://www.pharmafocusasia.com/strategy/indian-pharma-transition.

[23] MSF (2017) 'Don't Shut Down the Pharmacy of the Developing World' https://msfaccess.org/dont-shut-down-pharmacy-developing-world.

[24] Saad S, (2008) 'Aspen wins significant proportion of ARV Tender'. https://www.aspenpharma.com/2008/06/25/aspen-wins-significant-portion-arv-tender/.

enable local production has been recognised by the African Union Commission (AUC), who stress that *"[t]he AUC firmly believes that the TRIPS flexibilities present the same opportunity for African pharma as did the Indian Patent Act of 1970 for Indian industry. The Commission is convinced that full exploitation of the flexibilities would lead to a transformation of local industry"*.[25] Adoption and use of TRIPS flexibilities to enable industry growth is further recommended in the AUC's Pharmaceutical Manufacturing Plan for Africa (PMPA).[26]

Why a more flexible IP system would not harm foreign direct investment

Myth: Strong IP protections attract foreign direct investment (FDI).

Debunked: Factors such as market size, infrastructure and effective governance have been shown to be much more important, compared to IP protections, for determining whether to increase or withdraw FDI.

A further argument is that IP protections will attract foreign direct investment (FDI). Yet Baker et al., noted that *"the literature on FDI has consistently found that factors such as market size, infrastructure and effective governance (in the form of better business regulation) have been much more important [than IP] in determining flows of investment and therein, flows of information and know-how"*.[27] Smith et al., further add that "there is no conclusive evidence, however, suggesting that enhanced protection of intellectual-property rights leads to an increase in foreign direct investment". They also highlight the shortcomings of seeking to attract foreign direct investment through expanding intellectual property protections, noting that *"[t]he promise of increased foreign direct investment seems elusive and the comparative advantage of adoption of stronger intellectual-property rights tends to last only as long as the next developing country does not adopt them; once these rights are harmonised globally, no advantage accrues to one country compared with another"*.[28]

According to Kaplan, *"South Africa has attracted far less FDI than other countries whose IPR system appears to offer potential foreign investors weaker protection"*.[29] In South Africa, the expansion of IP protections in 1997 to comply with WTO TRIPS rules failed to attract increased foreign direct investment in the local pharmaceutical industry. Instead, expanded IP protections were met with substantial disinvestment in the country, as 35 pharmaceutical manufacturing plants (belonging mainly to originator producing pharmaceutical companies) were shut down in South Africa between 1994 and 2007.[30]

In research conducted on pharmaceutical production in South Africa, Naudé and Luiz concluded *"that intellectual property issues had little effect on the decisions made by [multinational corporations] to withdraw their manufacturing presence from South Africa."* They add that rather than expanding investment in countries with strengthened intellectual property protections, multinational pharmaceutical companies consolidated their operations in regions with skilled labour, low costs of labour and production and other economic incentives.[31] This trend is evident in India, which has attracted significant foreign investment in its pharmaceutical sector, despite not providing patents on pharmaceutical products until 2005 and progressively adopting TRIPS flexibilities thereafter.[32] Even Novartis who publicly threatened to withdraw their operations from India after the country applied TRIPS flexibilities to reject secondary patent applications on an important cancer medicine, has subsequently expanded its investments in the country.[33]

The above shows that there is no evidence that adoption and use of TRIPS flexibilities will harm foreign direct investment into South Africa; rather evidence suggests that the adoption of a flexible IP system that fosters local industry growth can attract investments as seen in India.

[25] AUC and UNIDO (2012) 'Pharmaceutical Manufacturing Plan for Africa Business Plan'. https://au.int/sites/default/files/pages/32895-file-pmpa_business_plan.pdf.

[26] AUC and UNIDO (2012) 'Pharmaceutical Manufacturing Plan for Africa Business Plan'. https://au.int/sites/default/files/pages/32895-file-pmpa_business_plan.pdf.

[27] Baker D, Jayadev A, and Stiglitz J., (2018) 'Innovation, Intellectual Property, and Development: A Better Set of Approaches for the 21st Century'. http://cepr.net/publications/reports/innovation-intellectual-property-and-development-a-better-set-of-approaches-for-the-21st-century.

[28] Smith RD, Correa C, Oh C, (2009) 'Trade, TRIPS, and pharmaceuticals' The Lancet, 373(9664), 684–691. https://www.ncbi.nlm.nih.gov/pubmed/19167054.

[29] Kaplan D (2009) 'Intellectual Property Rights and Innovation in South Africa: A Framework' The Economics of Intellectual Property in South Africa https://www.wipo.int/export/sites/www/ip-development/en/economics/pdf/wo_1013_e_ch_1.pdf.

[30] Maloney C, and Segal N, (2007) 'The Growth Potential of the Pharmaceuticals Sector in South Africa'. http://ipasa.co.za/Downloads/IPASA%20and%20Pharmaceutical%20Industry%20Profile/GENESIS%20Pharmaceuticals%20Report%20070529%20(2).pdf.

[31] Naude CW and Luiz J, (2013) 'An industry analysis of pharmaceutical production in South Africa'. https://www.researchgate.net/publication/286497235_An_industry_analysis_of_pharmaceutical_production_in_South_Africa.

[32] The Economic Times (2013) 'India receives highest FDI worth $1 billion in Pharma in April-June'. https://economictimes.indiatimes.com/industry/healthcare/biotech/pharmaceuticals/india-receives-highest-fdi-worth-1-billion-in-pharma-in-april-june/articleshow/22202828.cms.

[33] Chatterjee P (2018) 'Five years after the Indian Supreme Court's Novartis' https://www.ip-watch.org/2018/05/20/five-years-indian-supreme-courts-novartis-verdict/.

Why a more flexible IP system will not harm trade

Myth: A flexible IP system will harm trade

Debunked: Stringent IP protections can contribute to the trade deficit by preventing or delaying generic producers from entering the market.

Pharmaceutical imports are the fifth largest contributor to South Africa's trade deficit and reducing the trade deficit is a key goal of the Department of Trade and Industry.[34] Yet, overly stringent IP protections in South Africa contribute to the trade deficit by preventing or delaying local generic producers from entering the market.

Research by Fix the Patent Laws has shown that secondary patenting in South Africa generally prevents local manufactures from producing generic products long after they are already available in India, and forces patients to import high-cost originator products. This leads both to higher prices for local consumers and to greater outflows of money for originator procurement, which contributes to South Africa's pharmaceutical trade deficit.[35]

For example, secondary patents overturned in Europe and the U.S. were asserted in South Africa in 2011 to block local pharmaceutical producer Pharma Dynamics from marketing its registered generic birth control product (drospirenone and ethinyl estradiol) in the country until 2024. According to IMS data, Bayer earned more than ZAR 170 million from the sale of patented drospirenone and ethinyl estradiol products (Yasmin and Yaz) in South Africa's private sector in 2013 alone. If Pharma Dynamics' generic product was available, women in South Africa using Yasmin or Yaz would have the option to save approximately ZAR 50 million collectively per year through generic substitution (at prices offered by Pharma Dynamics) and substantial outflows of money could have been prevented.[36]

It is of course to be expected that the companies and countries benefiting from these outflows will oppose South Africa's proposed reforms.

Why IP reforms will not harm local innovation

Myth: Stringent IP protections promote local innovation

Debunked: Granting of undeserved patents does not incentivise meaningful innovation, rather it has the negative effect of reducing competition. Research has also shown that public financing plays a greater role in fostering local innovation than IP protection.

Those who support maximum IP protections also claim that stringent IP protections will promote local innovation. However, academics in South Africa have highlighted various shortcomings of the country's IP system in fostering and protecting local innovation.

From reviewing patent grant rates in multiple jurisdictions, Pouris and Pouris concluded that 80% of patents granted in South Africa would not have been granted if the country examined the merits of patent applications. The granting of unwarranted patents does not incentivise meaningful innovation and has the negative side-effect of reducing competition. Pouris and Pouris further showed

[34] Department of Trade and Industry Republic of South Africa (2011) 'The South African Pharmaceutical Sector Profile for the Consideration of Designation of Pharmaceutical Products in Terms of the PPFFA'.

[35] Tomlinson C, Moyo H, Rizvi Z, Waterhouse C, Meyer S, Low M. (2018) 'Exploring patent barriers to cancer treatment access in South Africa: 24 medicine case studies' https://www.canceralliance.co.za/wp-content/uploads/2017/10/Exploring-Patent-Barriers-to-Cancer-Treatment-Access-in-SA-24-Medicine-Case-Studies-October-2017.pdf.

See also: Fix the Patent Laws (2016) 'Patent Barriers to Medicine Access in South Africa: A Case for Patent Law Reform'. https://www.fixthepatentlaws.org/wp-content/uploads/2016/09/MSF-FTPL-report-FINAL-VERSION.pdf.

[36] Fix the Patent Laws (2016) 'Patent Barriers to Medicine Access in South Africa: A Case for Patent Law Reform' https://www.fixthepatentlaws.org/wp-content/uploads/2016/09/MSF-FTPL-report-FINAL-VERSION.pdf.

that South African inventors are often unable to protect their inventions abroad - finding that only 20% of academic patents reviewed also have protection abroad. The authors suggested that the high cost of filing patents abroad is likely a barrier to gaining IP protections outside of South Africa. Pouris and Pouris concluded *"that the current intellectual property rights regime not only fails to support the objectives of the national innovation system but also that it facilitates exploitation by foreign interests and creates substantial social costs"*.[37]

Similarly, Berger and Rens found that only one third of patents granted in South Africa to domestic inventors between 2005 and 2015 had protection abroad - although the rates were far higher for publicly funded research organizations and universities at 76,2% and 60,6%, respectively. Berger and Rens suggested that the low rates of protection abroad may indicate that many patents are granted to local inventors on dubious claims that do not hold up against patentability criteria in countries with examination systems and suggested that current patent incentives in South Africa may be inadequate in fostering genuine innovation. Berger and Rens added, however, that publicly funded research institutes and universities higher success rates in gaining protection abroad strongly suggests *"that a primary driver of quality local innovation is the availability of public funding for research and development, and not the existence of a permissive IP regime."*[38]

Evidence suggests that public financing plays a greater role in fostering local innovation than IP protection. The studies also indicate that adoption of stricter patentability criteria and an examination system is necessary to address the granting of unmerited patents to foreign corporations, while also making local inventors more competitive globally. However, even with the adoption of proposed reforms, local inventors will continue to be disadvantaged by a global IP system that facilitates excessive patent filing by large foreign corporations locally, while creating costs constraints for local inventors seeking global protections.

Why a more flexible IP system will not harm health innovation

Myth: IP protection is needed for incentivising live-saving innovations

Debunked: R&D in health innovation has largely been driven by profit. A profit driven patent approach has led pharmaceutical companies to invest in R&D with predictable profitability, rather than investing in risky early stage research toward the development of truly innovative new drugs

It has also been argued that strong IP protections are a necessary instrument for incentivising needed innovations, evidence shows that the global expansion and harmonisation of IP protections under TRIPS has failed to stimulate genuine and needed health innovations.

Leading health economist Mazzucato argues that by incentivizing R&D towards maximizing profits rather than health benefits, IP incentives fail to deliver genuine needed innovation. Mazzucato shows that the profit driven patent approach leads companies to invest in R&D with predictable profitability, such as the development of 'me-too' products able to benefit from existing profitable markets, rather than investing in risky early stage research toward the development of truly innovative new drugs.[39]

Profit driven R&D investment by industry has led to a plethora of me-too products that offer little therapeutic improvements over existing drugs. Research conducted in the US and France demonstrates that the vast majority of newly registered medicines offer no new therapeutic benefits to patients beyond what is offered by existing products.[40] Fojo et al argue that the pursuit of me-too products by industry stifles innovative progress and, in the field of cancer, has led to a plethora of high-cost products that offer marginal benefits to patients.[41]

In addition to incentivising the development of me-too products able to gain market share, evidence demonstrates that the patent system incentivises R&D towards incremental innovation in pursuit of secondary patents that extend market monopolies beyond 20 years.

While rates of introduction of truly innovative new drugs arguably declined following TRIPS adoption, rates of secondary patenting sky-rocketed.[42] Unlike primary patents that are typically granted

[37] Pouris A and Pouris A (2011) 'Patents and economic development in South Africa: Managing intellectual property rights' http://www.scielo.org.za/scielo.php?script=sci_arttext&pid=S0038-23532011000600008.

[38] Berger J and Rens A, (2018) 'Innovation and Intellectual Property in South Africa: The Case for Reform.' http://ip-unit.org/wp-content/uploads/2018/05/Innovation-IP-in-SA.pdf.

[39] Mazzucato M, (2016) 'How tax payer prop up big pharma, and how to cap that'. https://www.latimes.com/opinion/op-ed/la-oe-1027-mazzucato-big-pharma-prices-20151027-story.html.

[40] Prescrire (2015) 'New drugs and indications in 2014'. 35(376):132-136. **See also** Hubbard T and Love J, (2004) 'A New Trade Framework for Global Healthcare R&D' https://doi.org/10.1371/journal.pbio.0020052.

[41] Fojo T, Mailankody S and Lo A (2014) 'Unintended consequences of expensive cancer therapeutics – the pursuit of marginal indications and a me-too mentality that stifles innovation and creativity'. DOI:10.1001/jamaoto.2014.1570.

[42] Sampat B. (2009) 'Academic Patents and Access to Medicines in Developing Countries' doi:10.2105/AJPH.2007.128769. **See also** European Commission (2008) 'Pharmaceutical Sector Inquiry Final Report' http://ec.europa.eu/competition/sectors/pharmaceuticals/inquiry/staff_working_paper_part1.pdf.

on a medicine's base compound or biologic molecule, secondary patents are granted on a wide range of claims – including minor modifications to, and new uses of, existing drugs.[43]

According to an enquiry by the EU, secondary patents are commonly pursued as part of a 'tool-box' of strategies used by companies to extend their commercial monopolies.[44] Kapczynski et al., highlighted that secondary patents are more aggressively sought on best-selling drugs in an effort to 'evergreen' commercial monopolies on top earning products.[45]
While secondary patents are granted the same 20-year monopoly protection as primary claims, they are far more likely to be overturned when challenged in court – given their dubious claims of novelty, inventiveness and usefulness.[46] Yet, in South Africa which commonly grants secondary patents rejected in other jurisdictions, court challenges on secondary patents are rare.[47] This is likely due to the country's relatively small market size, regulatory disincentives, and the tendency of South African courts to *"[apply] a low bar for novelty and inventiveness and [err] in favour of upholding the patent holder's protections over public interest"*.[48] As a result, weak secondary patents granted in South Africa and held by foreign corporations commonly inhibit access to more affordable generic products in South Africa, long after they enter the global market.

[43] European Commission (2008) 'Pharmaceutical Sector Inquiry Final Report'. http://ec.europa.eu/competition/sectors/pharmaceuticals/inquiry/staff_working_paper_part1.pdf.

[44] European Commission (2008) 'Pharmaceutical Sector Inquiry Final Report'. http://ec.europa.eu/competition/sectors/pharmaceuticals/inquiry/staff_working_paper_part1.pdf.

[45] Kapczynski A; Park C and Sampat B (2012) 'Polymorphs and Prodrugs and Salts (Oh My!): An Empirical Analysis of "Secondary" Pharmaceutical Patents' https://doi.org/10.1371/journal.pone.0049470.

[46] Hemphill S and Sampat B, (2011) 'Weak Patents Are a Weak Deterrent: Patent Portfolios, the Orange Book Listing Standard and Generic Entry in Pharmaceuticals'.

[47] Tomlinson C, Waterhouse C, Hu Y Q, Meyer S, Moyo H, (2019) 'How patent law reform can improve affordability and accessibility of medicines in South Africa: Four medicine case studies' DOI:10.7196/SAMJ.2019.v109i6.14001.

[48] Tomlinson C, Waterhouse C, Hu Y Q, Meyer S, Moyo H, (2019) 'How patent law reform can improve affordability and accessibility of medicines in South Africa: Four medicine case studies' DOI:10.7196/SAMJ.2019.v109i6.14001.

The impact of IP frameworks on the development of new treatments for neglected diseases

While some may argue that IP protections are necessary to foster health innovation, evidence demonstrates that IP protections fail to incentivize innovation for health issues faced in many developing countries. Instead, public financing plays a far greater role in supporting the advancement of health technologies needed in developing countries.

As highlighted above, the patent system incentivises innovation investment towards maximising profits, rather than maximising health benefits. As a result, the pharmaceutical industry routinely ignores health issues that are not viewed as sufficiently profitable, including diseases primarily prevalent in developing countries.

Recognising innovation inequality, Sutz writes *"The big pharmaceutical enterprises, through prices, intellectual property rights, and their research agenda… define who will have access to cures and who will not; and also, which problems will be tackled and which will continue to be rather invisible and ignored by research and innovation."*[49] Correa adds *"the current R&D model, based on patents and market-oriented research, fails to generate new health technologies to face the global challenges arising from existing health needs, particularly in developing countries."*[50]

While neglected diseases (faced primarily in developing countries) account for approximately 12% of the total global burden of disease, only 4% of therapeutic products registered between 2000 and 2011 included an indication for a neglected disease.[51] Over half of the global burden of neglected diseases occur in African countries.[52] According to the United Nation's High-Level Panel on Access to Medicines *"chronic underinvestment in neglected diseases by industry results in inadequate, inefficient or non-existent means to prevent, diagnose and treat them"*.[53] The health consequences for developing countries are severe. For example, prior to the 2014 Ebola outbreak in West Africa, research towards an Ebola vaccine stalled due to lack of investment which resulted in thousands of potentially avoidable deaths.[54] Chronic underinvestment has also hampered innovative progress for tuberculosis – a disease for which only two new medicines have been registered in the past 50 years.[55] As a result, drug resistant TB patients in South Africa and elsewhere must endure long and difficult treatment regimens with low success rates. The lack of investment by industry in developing country health issues has left public funders to foot the bills for critical R&D to address developing country diseases. Public funders provide more than 60% of funding for neglected disease R&D.[56]

Evidence clearly demonstrates that IP fails to incentivise adequate R&D investment by industry to address diseases affecting poor populations and countries, but rather incentivises R&D towards profit maximisation. As a result, health agencies in Africa and other developing regions are left with inadequate tools to respond to pressing health needs facing their populations.

[49] Sutz J, (2015) 'Is there a role for innovation in health equity?' https://www.researchgate.net/publication/274073639_Innovation_Systems_Development_and_Health_an_Introduction.

[50] Correa C, (2012) 'Towards a New Model for Pharmaceutical Research'. https://www.researchgate.net/publication/233889507_Towards_a_new_model_for_pharmaceutical_research.

[51] United Nations (2016) 'Report of the United Nations High-Level Panel on Access to Medicines'. http://www.unsgaccessmeds.org/final-report .

[52] WHO Disease burden – neglected tropical diseases http://www.aho.afro.who.int/profiles_information/index.php/AFRO:Disease_burden_-_Neglected_tropical_diseases.

[53] United Nations (2016) 'Report of the United Nations High-Level Panel on Access to Medicines'. http://www.unsgaccessmeds.org/final-report.

[54] Greenberg A and Kiddel-Monroe R (year) 'ReRouting Biomedical Innovation: observation from mapping the alternative innovation landscape' doi:10.1186/s12992-016-0190-8.

[55] Green A (2017) 'Access to new TB drugs for SA'. https://health-e.org.za/2017/10/18/access-new-tb-drugs-sa/

[56] G-Finder (2017) 'Neglected Disease Research and Development: Reflecting on a decade of global investment'. https://www.policycuresresearch.org/g-finder-2017/.

The impact of IP frameworks on R&D expenditure

Proponents for stringent IP protections commonly claim that efforts to restrict patenting and adopt public health safeguards will harm biomedical innovation by removing industry's ability to recoup R&D costs and invest in further research. This claim ignores the large role of taxpayer financing in funding R&D – including early stage risky drug development and drugs for neglected diseases – and does not withstand scrutiny as available data demonstrates that R&D expenditure is dwarfed by industry expenditure on profits, stock-buy backs and marketing.

In the past decade, spending on dividends (profits paid to shareholders) and stock buy-backs (which increase the value of shareholders stocks) has outpaced spending on R&D by pharmaceutical companies in the US.[57] Lazonick et al., argued that the direction of US pharmaceutical companies spending seeks to maximise shareholder value (MSV), at the expense of innovation stating that *"MSV is a profit-driven ideology that results in high drug prices, restricted access to existing medicines, and stifled pharmaceutical innovation."*[58]

Evidence that spending on marketing and advertising outpaces spending on R&D by pharmaceutical companies further undermines the argument that high medicine prices are essential to recouping R&D costs.[59] Health economist Mazzucatto states that *"the myth of ever increasing R&D costs (now into the $1-2 Bn range) to justify high medicines prices does not hold up to data scrutiny, and is toppled by much higher marketing expenditures. Instead, it points to massive inefficiencies in the R&D process that are being sanctioned in the current model in which a highly monopolized and subsidized market will pay any price for a new medicine."*[60]

Comparisons of sales income with R&D spending for cancer medicines have further demonstrated that sales income vastly exceeds R&D spending, and that R&D spending is fully recouped in the first few years after marketing approval.[61] A recently published paper comparing cumulative sales data for cancer medicines approved in the U.S. between 1989 and 2017 with estimated R&D costs found that *"the returns from cancer drugs are much higher than what would be considered a justifiable return required for rewarding and incentivizing innovation, both in economic terms and by reasonableness."*[62]

In other words, evidence reveals that the pharmaceutical industry is exploiting extended patent monopolies to maximise profits, while reinvesting only a small portion of its revenue into R&D despite repeated claims that extended patent monopoly periods are needed to recoup R&D costs. At the same time, industry is aggressively seeking to obscure and hide data on its actual R&D expenditure, as greater transparency would undermine their narrative that expansive IP protection and high medicine prices are required to enable innovation of new health technologies. Most recently, industry opposed the inclusion of language on R&D cost transparency in a World Health Assembly resolution on price transparency.[63]

[57] Lazonick W, Hopkins M, Jacobson K, Sakinç ME, and Tulum O, (2017) 'US Pharma's financialised business model'. https://www.ineteconomics.org/uploads/papers/WP_60-Lazonick-et-al-US-Pharma-Business-Model.pdf.

[58] Lazonick W, Hopkins M, Jacobson K, Sakinç ME, and Tulum O, (2017) 'US Pharma's financialised business model'. https://www.ineteconomics.org/uploads/papers/WP_60-Lazonick-et-al-US-Pharma-Business-Model.pdf.

[59] Mazzucato M (2016) 'Contribution to the United Nations High-Level Panel on Access to Medicines' http://www.unsgaccessmeds.org/inbox/2016/2/28/mariana-mazzucato?rq=marketing.

[60] Mazzucato M (2016) 'Contribution to the United Nations High-Level Panel on Access to Medicines' http://www.unsgaccessmeds.org/inbox/2016/2/28/mariana-mazzucato?rq=marketing.

[61] Prasad V, and Mailankody S (2017) 'Research and Development Spending to Bring a Single Cancer Drug to Market and Revenues After Approval' doi: 10.1001/jamainternmed.2017.3601. See also Tay-Teo K, Ilbawi A, Hill SR (2019) 'Comparison of Sales Income and Research and Development Costs for FDA-Approved Cancer Drugs Sold by Originator Drug Companies' doi:10.1001/jamanetworkopen.2018.6875.

[62] Tay-Teo K, Ilbawi A, Hill SR (2019) 'Comparison of Sales Income and Research and Development Costs for FDA-Approved Cancer Drugs Sold by Originator Drug Companies' doi:10.1001/jamanetworkopen.2018.6875.

[63] Cullinan K (2019) 'Medicine transparency is a sticky issue at WHA'. https://health-e.org.za/2019/05/27/medicine-price-transparency-is-a-sticky-issue-at-wha/.


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CONCLUSION

Those who have benefited from strict IP systems claim that the reforms outlined in South Africa's new IP Policy will harm economic development and innovation. However, there is little evidence to support these claims.

The expansive IP protections required under TRIPS obligate developing countries to provide stricter IP protections than those upheld by developed countries during their periods of rapid growth and industrial development. This prevents the use of, or places exorbitant costs on the use of, knowledge and technologies generated in other countries, which is often critical for transitioning economies into innovative economies able to recoup rewards from IP protections.

In South Africa, there is little evidence that IP protections, or their 1997 expansion, have helped local inventors. Rates of patenting by foreign corporations in South Africa dwarfs rates of patenting by local inventors and local inventors are often unable to secure protections abroad.[64]

Evidence further demonstrates that patents held by foreign corporations in South Africa are commonly rejected (or granted on a smaller scope of protection following rejection of the broader claim) in other jurisdictions.[65] For example, research by Fix the Patent Laws showed that South Africa granted 32 secondary patents on the cancer medicines lenalidomide. For all 32 patents granted in South Africa, a matching patent application (or divisional application thereof) was withdrawn or rejected in at least one other jurisdiction.[66] The granting and upholding of secondary patents rejected and withdrawn outside of the country results in significant economic and social harms within South Africa.

The granting of undeserved patents requires substantial outflows of money from South Africa to procure high cost medicines from foreign industry. It also delays generic manufacture in South Africa - typically long after generic products are already brought to market in India.[67] Delayed generic production impedes the ability of local producers to compete in both the local and international generic markets, where early entry is often key to market share.

[64] Berger J and Rens A,(2018) 'Innovation and Intellectual Property in South Africa: The Case for Reform' http://ip-unit.org/wp-content/uploads/2018/05/Innovation-IP-in-SA.pdf.

[65] Tomlinson C, Moyo H, Rizvi Z, Waterhouse C, Meyer S, Low M. (2018) 'Exploring patent barriers to cancer treatment access in South Africa: 24 medicine case studies' https://www.cancerallliance.co.za/wp-content/uploads/2017/10/Exploring-Patent-Barriers-to-Cancer-Treatment-Access-in-SA-24-Medicine-Case-Studies-October-2017.pdf.

[66] Tomlinson C, Waterhouse C, Hu Y Q, Meyer S, Moyo H. (2019). 'How patent law reform can improve affordability and accessibility of medicines in South Africa: Four medicine case studies.' DOI:10.7196/SAMJ.2019.v109i6.14001. See also Fix the Patent Laws (2016) 'Patent Barriers to Medicine Access in South Africa: A Case for Patent Law Reform' https://www.fixthepatentlaws.org/wp-content/uploads/2016/09/MSF-FTPL-report-FINAL-VERSION.pdf.

[67] Tomlinson C, Moyo H, Rizvi Z, Waterhouse C, Meyer S, Low M. (2018) 'Exploring patent barriers to cancer treatment access in South Africa: 24 medicine case studies' https://www.cancerallliance.co.za/wp-content/uploads/2017/10/Exploring-Patent-Barriers-to-Cancer-Treatment-Access-in-SA-24-Medicine-Case-Studies-October-2017.pdf.

Research by Fix the Patent Laws has further shown that the granting of undeserved patents places high financial and health costs on patients, government and private health insurers by forcing buyers to pay excessive medicine costs or patients to forgo treatment.

A recently published SA Medical Journal review of patents granted on four cancer and hepatitis medicines showed that secondary patents granted in South Africa significantly extend companies market monopolies. For three of the medicines, secondary patents extended market monopolies more than a decade after the initial 20-year patent monopoly ended. For all four medicines, generic products were already available in India at a fraction of the cost of patented products in South Africa (between 5 and 13%). None of the four medicines reviewed were available in South Africa's public health sector, likely due to cost constraints.[68] Given that the public sector serves more than 80% of the population, access to more affordable products that allow provision in this sector would significantly enhance equitable health care access in the country.

This paper debunks claims that the most stringent IP protections bolster economic development and innovation and provides evidence that overly stringent IP protections can impede these goals. It further highlights the high financial, social and health costs of overly stringent IP approaches. Moreover, it provides evidence to support the case for reform of South Africa's patent laws in line with the country's new IP policy to adopt a strategic IP approach that reflects and responds to the health, social and economic needs of the country.

"*Emerging economies should take the lead in creating a balanced IP system that recognizes the importance of knowledge for development, growth, and wellbeing. What matters is not only the production of knowledge, but also that it is used in ways that put people's health and welfare ahead of corporate profits. South Africa's potential decision to enable access to medicine may be an important milestone on the road toward that goal.*

- Joseph E Stiglitz, Nobel Prize winning economist"

[68] Tomlinson C, Waterhouse C, Hu Y Q, Meyer S, Moyo H. (2019) 'How patent law reform can improve affordability and accessibility of medicines in South Africa: Four medicine case studies' DOI:10.7196/SAMJ.2019.v109i6.14001.

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